In the House of Representatives, U. S.,

October 7 (legislative day, October 6), 1994.

Resolved, That the bill from the Senate (S. 784) entitled ''An Act to amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes'', do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Dietary Supplement Health and Education Act of 1994''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

(c) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

Congress finds that—

(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

(5) preventive health measures, including education, good nutrition, and appropriate use of safe

nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

(B) the industry consistently projects a positive trade balance; and

(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;

(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

SEC. 3. DEFINITIONS.

(a) DEFINITION OF CERTAIN FOODS AS DIETARY SUPPLEMENTS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ff) The term 'dietary supplement'—

''(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

''(A) a vitamin;

''(B) a mineral;

''(C) an herb or other botanical;

''(D) an amino acid;

''(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

''(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

''(2) means a product that—

''(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

''(ii) complies with section 411(c)(1)(B)(ii);

''(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

''(C) is labeled as a dietary supplement; and

''(3) does—

''(A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

''(B) not include—

''(i) an article that is approved as a new drug under section 505, certified as an

antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

''(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.''.

(b) EXCLUSION FROM DEFINITION OF FOOD ADDITIVE.—Section 201(s) (21 U.S.C. 321(s)) is amended—

(1) by striking ''or'' at the end of subparagraph (4);

(2) by striking the period at the end of subparagraph (5) and inserting ''; or''; and

(3) by adding at the end the following new subparagraph:

''(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.''.

(c) FORM OF INGESTION.—Section 411(c)(1)(B) (21 U.S.C. 350(c)(1)(B)) is amended—

(1) in clause (i), by inserting ''powder, softgel, gelcap,'' after ''capsule,''; and

(2) in clause (ii), by striking ''does not simulate and''.

SEC. 4. SAFETY OF DIETARY SUPPLEMENTS AND BURDEN OF PROOF ON FDA.

Section 402 (21 U.S.C. 342) is amended by adding at the end the following:

''(f)(1) If it is a dietary supplement or contains a dietary ingredient that—

''(A) presents a significant or unreasonable risk of illness or injury under—

''(i) conditions of use recommended or suggested in labeling, or

''(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

''(B) is a new dietary ingredient for which there is inadequate information to provide reasonable as-

surance that such ingredient does not present a significant or unreasonable risk of illness or injury;

''(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or

''(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

''(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.''.

SEC. 5. DIETARY SUPPLEMENT CLAIMS.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403A the following new section:

''DIETARY SUPPLEMENT LABELING EXEMPTIONS

''SEC. 403B. (a) IN GENERAL.—A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

''(1) is not false or misleading;

''(2) does not promote a particular manufacturer or brand of a dietary supplement;

''(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

''(4) if displayed in an establishment, is physically separate from the dietary supplements; and

''(5) does not have appended to it any information by sticker or any other method.

''(b) APPLICATION.—Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

''(c) BURDEN OF PROOF.—In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.''.

SEC. 6. STATEMENTS OF NUTRITIONAL SUPPORT.

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:

''(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

''(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

''(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

''(C) the statement contains, prominently displayed and in boldface type, the following: 'This statement has not been evaluated by the Food and Drug

Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.'.

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.''.

SEC. 7. DIETARY SUPPLEMENT INGREDIENT LABELING AND NUTRITION INFORMATION LABELING.

(a) MISBRANDED SUPPLEMENTS.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''(s) If—

''(1) it is a dietary supplement; and

''(2)(A) the label or labeling of the supplement fails to list—

''(i) the name of each ingredient of the supplement that is described in section 201(ff); and

''(ii)(I) the quantity of each such ingredient; or

''(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

''(B) the label or labeling of the dietary supplement fails to identify the product by using the term 'dietary supplement', which term may be modified with the name of such an ingredient;

''(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

''(D) the supplement—

''(i) is covered by the specifications of an official compendium;

''(ii) is represented as conforming to the specifications of an official compendium; and

''(iii) fails to so conform; or

''(E) the supplement—

''(i) is not covered by the specifications of an official compendium; and

''(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

''(II) fails to meet the quality (including tablet or capsule disintegration), purity, or

compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.''.

(b) SUPPLEMENT LISTING ON NUTRITION LABELING.—Section 403(q)(5)(F) (21 U.S.C. 343(q)(5)(F)) is amended to read as follows:

''(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that—

''(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

''(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

''(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

''(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.''.

(c) PERCENTAGE LEVEL CLAIMS.—Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding after clause (E) the following:

''(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.''

(d) VITAMINS AND MINERALS.—Section 411(b)(2) (21 U.S.C. 350(b)(2)) is amended—

(1) by striking ''vitamins or minerals'' and inserting ''dietary supplement ingredients described in section 201(ff)'';

(2) by striking ''(2)(A)'' and inserting ''(2)''; and

(3) by striking subparagraph (B).

(e) EFFECTIVE DATE.—Dietary supplements—

(1) may be labeled after the date of the enactment of this Act in accordance with the amendments made by this section, and

(2) shall be labeled after December 31, 1996, in accordance with such amendments.

SEC. 8. NEW DIETARY INGREDIENTS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

''NEW DIETARY INGREDIENTS

''SEC. 413. (a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:

''(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

''(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any

citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

''(b) PETITION.—Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, United States Code, the decision of the Secretary shall be considered final agency action.

''(c) DEFINITION.—For purposes of this section, the term 'new dietary ingredient' means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.''.

SEC. 9. GOOD MANUFACTURING PRACTICES.

Section 402 (21 U.S.C. 342), as amended by section 4, is amended by adding at the end the following:

''(g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

''(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.''.

SEC. 10. CONFORMING AMENDMENTS.

(a) SECTION 201.—The last sentence of section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended to read as follows: ''A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food,

dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.''.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(u) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.''.

(c) SECTION 403.—Section 403 (21 U.S.C. 343), as amended by section 7, is amended by adding after paragraph (s) the following:

''A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.''.

SEC. 11. WITHDRAWAL OF THE REGULATIONS AND NOTICE.

The advance notice of proposed rulemaking concerning dietary supplements published in the Federal Register of June 18, 1993 (58 FR 33690–33700) is null and void and of no force or effect insofar as it applies to dietary supplements. The Secretary of Health and Human Services shall publish a notice in the Federal Register to revoke the item declared to be null and void and of no force or effect under subsection (a).

SEC. 12. COMMISSION ON DIETARY SUPPLEMENT LABELS.

(a) ESTABLISHMENT.—There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the ''Commission'').

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Commission shall be composed of 7 members who shall be appointed by the President.

(2) EXPERTISE REQUIREMENT.—The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. Members and staff of the Commission shall be without bias on the issue of dietary supplements.

(c) FUNCTIONS OF THE COMMISSION.—The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for

dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

(d) ADMINISTRATIVE POWERS OF THE COMMISSION.—

(1) HEARINGS.—The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.

(2) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

(e) REPORTS AND RECOMMENDATIONS.—

(1) FINAL REPORT REQUIRED.—Not later than 24 months after the date of enactment of this Act, the

Commission shall prepare and submit to the President and to the Congress a final report on the study required by this section.

(2) RECOMMENDATIONS.—The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.

(3) ACTION ON RECOMMENDATIONS.—Within 90 days of the issuance of the report under paragraph (1), the Secretary of Health and Human Services shall publish in the Federal Register a notice of any recommendation of Commission for changes in regulations of the Secretary for the regulation of dietary supplements and shall include in such notice a notice of proposed rulemaking on such changes together with an opportunity to present views on such changes. Such rulemaking shall be completed not later than 2 years after the date of the issuance of such report. If such rulemaking is not completed on or before the expiration of such 2 years, regulations of the Secretary published in 59 FR 395–426 on January 4, 1994, shall not be in effect.

SEC. 13. OFFICE OF DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Title IV of the Public Health Service Act is amended by inserting after section 485B (42 U.S.C. 287c–3) the following:

''Subpart 4—Office of Dietary Supplements

''SEC. 485C. DIETARY SUPPLEMENTS.

''(a) ESTABLISHMENT.—The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

''(b) PURPOSE.—The purposes of the Office are—

''(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

''(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

''(c) DUTIES.—The Director of the Office of Dietary Supplements shall—

''(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

''(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

''(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

''(A) dietary intake regulations;

''(B) the safety of dietary supplements;

''(C) claims characterizing the relationship between—

''(i) dietary supplements; and

''(ii)(I) prevention of disease or other health-related conditions; and

''(II) maintenance of health; and

''(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

''(4) compile a database of scientific research on dietary supplements and individual nutrients; and

''(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

''(d) DEFINITION.—As used in this section, the term 'dietary supplement' has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.''.

(b) CONFORMING AMENDMENT.—Section 401(b)(2) of the Public Health Service Act (42 U.S.C. 281(b)(2)) is amended by adding at the end the following:

''(E) The Office of Dietary Supplements.''.

Attest:

Clerk.

103D CONGRESS
2D SESSION

S. 784

AMENDMENT